

Question and answer session

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Professor Martin Cowie: Perhaps I can ask John McMurray to clarify the situation about diabetes in the EPHEUS study?

Professor John McMurray: As you know the highest risk patients after an infarct are women, the elderly, diabetics and those with either heart failure or left ventricular systolic dysfunction, and those groups overlap enormously. So, for example, if you are diabetic you are much more likely to develop heart failure even if you don't have a low ejection fraction after infarction. The idea behind EPHEUS, as was the idea behind similar trials of ACE inhibitor and ARB after myocardial infarction, was to identify a high risk subset of patients in whom to test the treatment. EPHEUS simply identified patients as being at very high risk by having a low ejection fraction and evidence of heart failure or diabetes. So even though we are focusing on heart failure today, another route to get into EPHEUS was to have diabetes and a low ejection fraction, as opposed to signs of heart failure. I have not been able to tease out how many patients entered the trial on the basis of having diabetes and low ejection fraction, but without frank heart failure. I think it was probably only a small proportion.

Question: I wonder if John McMurray could say a little about the side effect profile of eplerenone, because in real life spironolactone does cause us problems with hyperkalaemia, renal impairment, and hypotension? Is eplerenone going to be better than that?

Professor McMurray: That is an extremely good point. I think randomised trials may give us a very favourable idea of adverse event profiles. You are correct in pointing out that the experience of spironolactone in the real world has been quite alarming in some ways because it has not been used properly. I am sure if these drugs are used properly, the benefit:risk balance is very much in favour of their use. In terms of the adverse effects you can expect with eplerenone, the adverse event profile is essentially the same as that of spironolactone, with the exception of the oestrogenic type adverse events, so for example in men avoidance of painful gynaecomastia, erectile dysfunction, and so on. In terms of renal dysfunction, hyperkalaemia and so on then you can expect to see the same problems.

Professor John Cleland: I wonder how many people have in place an infrastructure that allows them to follow their patients as they were followed in the ACE inhibitor, β blocker or aldosterone antagonist trials. We only know that these treatments are safe and effective when administered in the way that they were administered in the clinical trials. Until recently, I think we have not been paying attention to the care that was taken in the clinical trials to deliver the treatment. I think the situation may now be improving, but we have a tremendous way to go to put in place the infrastructure that allows proper organised care. In our own

area we spend £15 million per year on "disorganised" care for heart failure and about £100 000 on organised care, so something has got to change!

Professor Cowie: On a slightly more positive note, we have made a lot of progress with β blockade in chronic heart failure, which also needs very careful introduction, and monitoring, so we have a precedent, but I agree with your point.

Professor Cowie: Dr McDonagh, could you comment on the British Society of Heart Failure's current endeavours to find something measurable to collect data on heart failure care across the country, as Professor Pearson has challenged us to do?

Dr Theresa McDonagh: This is much more difficult in heart failure than for myocardial infarction. In the BSHF we have tried to address this issue by drafting standards of care for heart failure, against which we can assess care. We hope to publish the standards document in the near future. It provides standards for staffing levels for doctors with an interest in heart failure, and the number of heart failure nurses in hospital or working between hospital and primary care trusts. Additionally, we can look at things like ACE inhibitor and β blocker usage, hospital admissions, and all cause outcome. We have certainly begun this process.

Question: Professor Pearson, you showed one side of the coin, how to promote and sustain best practice. But, of course, one of the barriers to best practice is our failure to stamp out entrenched bad practice. How do you suggest that you could use your methodologies to enable us to do that?

Professor Mike Pearson: So far, at the Royal College of Physicians we have worked on the basis that if we get the data back, we can get people engaged with multidisciplinary meetings and get them to look at their own practice. If they know there is going to be further measurement they at least know that someone is watching. I think we do need to be more proactive in getting into hospitals and helping those who have difficulties. One of the things that the Health Foundation is looking for in its research bids at the moment is new interventions to get into hospital, and we are looking at a number of possible routes including linking management and clinicians together in action plans. Something has to happen, and we need to look again at peer review, which I know the British Cardiac Society has been very keen on.

Question: You have shown us the carrot, but what is the stick?

Professor Pearson: There will be a stick in that all the audit data will ultimately go to the Healthcare Commission; we will not be able to hold it to ourselves. They will have an inspection regime. I am looking at it, however, from a positive professional point of view, trying to lead people forward rather than hitting them with sticks.